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Via Federal Express

TSCA Confidential Business Information Center (7407M)

EPA East - Room 6428 Attn: Section 8(e)

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004-3302

CBIC Control Number

364610

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Subject: Notice in Accordance with TSCA Section 8(e): Results of an acute eye irritation study in rabbits with an experimental pesticide formulation containing 2 active ingredients.

Dear Section 8(e) Coordinator:

[REDACTED] is submitting results of an eye irritation study with an experimental pesticide formulation containing 2 active ingredients, conducted by [REDACTED].

Active Ingredients:

1. [REDACTED]

2. [REDACTED]

The potential of test substance to cause damage to the conjunctiva, iris or cornea was assessed by a single ocular application of 0.1 mL of the undiluted test item to one eye of one New Zealand White rabbit. No additional animals were tested due to serious eye damage in this animal.

The eye was rinsed with tap water no less than 24 hours after administration. The ocular reactions were assessed approximately 1, 24, 48 and 72 hours after administration and in weekly intervals until day 28. Additional eye examinations were performed following the instillation of a fluorescein solution starting at 24 h after administration until day 7 (reversibility of corneal lesions).

The following test item-related clinical observations were recorded during the course of the study:

- Slight to moderate corneal opacity (grade 1-2)
- Moderate iritis (grade 1)
- Slight conjunctival redness (grade 1)
- Slight to moderate conjunctival chemosis (grade 1-2)
- Obvious discharge (grade 2)
- Additional findings like contracted pupil, desquamation of corneal epithelium, corneal lesions detected with the aid of fluorescein (grade 3 - 4), mucosal proliferation and injected scleral vessels in a circumscribed or circular area were noted in the animal during the whole observation period of 28 days.

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In one single animal the ocular reactions were not reversible within 28 days after administration. Slight conjunctival chemosis, desquamation of corneal epithelium, injected scleral vessels in a circumscribed area and mucosal proliferation were still observed at study termination on day 28.

Mean scores calculated for the single animal over 24, 48 and 72 hours were 1.7 for corneal opacity, 1.0 for iris lesions, 1.0 for redness of the conjunctiva and 2.0 for chemosis.

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Considering the irreversibility of the described ocular reactions, test substance causes serious eye damage under the test conditions chosen.

██████████ understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,